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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,336	04/26/2007	Claudia Wopmann	051058-1000	2542
84717	7590	02/12/2010		
Nixon Peabody LLP 401 9th Street N.W. Suite 900 Washington, DC 20004			EXAMINER ZARA, JANE J	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 02/12/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Attachment

Maintained Rejections

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-56, 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed 11-13-09, and as set forth below. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 1-13-10 have been fully considered but they are not persuasive. Applicant argues that adequate written description has been provided for the expansive genus of inhibitory compounds claimed. Applicant cites paragraphs in the instant disclosure that generally describe dsRNA molecules potentially having non-complementary sequences between the antisense strand of the siRNA and its intended target gene sequence, as well as having non-complementary sequences between the sense and antisense strands of the siRNA molecules. These sweeping general descriptions, however, do not compensate for the lack of adequate description of dsRNA molecules which are presumed to have the utility of RNA interference activity,

yet have non-homologous sequences located somewhere in the siRNA molecule, and comprise the termini as instantly claimed.

Applicant points to Example 5, which provides three different dsRNA molecules comprising the motifs claimed with regard to the GC base pair contents and positioning within the siRNA molecules, as well as with respect to the overhangs and their nucleotide compositions. Applicant also points to Example 6, which does not aid in fulfilling the required written description because this merely teaches that an siRNA comprising more GC base pairs has a higher  $T_m$  than one which has less GC base pairs, which is predictable. Since nucleases are well known to act on single strands, and exonucleases are well known to act on the termini of single strands, it would be no surprise that double stranded oligonucleotides with GC base pairs on their termini (acting as clamps) would provide for better annealing between strands at those termini, and thus would impart more resistance from exonuclease degradation when base paired. But a higher  $T_m$  between antisense and sense strands in an siRNA molecule, while imparting enhanced resistance from nuclease degradation, does not necessarily impart RNA interference capability. For these reasons, adequate written description has not been provided for the broad genus of inhibitory compounds claimed, and which provide for the presumed functions claimed, of possessing RNA interfering activity as well as possessing enhanced stability from nuclease degradation.

For these reasons, the instant rejection is maintained.

### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore, can be reached on (571) 272-2914. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**Jane Zara**

**2-4-10**

/Jane Zara/

Primary Examiner, Art Unit 1635